OCT 02 2008

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## 510(k) SUMMARY (As Required per 21 CFR 807.92(c))

K082107

### GENERAL INFORMATION:

| | |
|---|---|
| **510k Owner's Name**<br>**Address** | Bovie Medical<br>3200 Tyrone Boulevard, Suite A<br>St. Petersburg, Florida 33710-2902 |
| **Contact Person** | Richard A. Kozloff<br>Vice-President; Quality Assurance/Regulatory Affairs<br>Telephone #: (727) 803-8513<br>FAX Number: (727) 347-9144 |
| **Date Prepared:** | 07/22/2008 |

### DEVICE DESCRIPTION:

| | |
|---|---|
| **Trade Name:** | Bovie ICON GP General Purpose Electrosurgical Generator |
| **Common Name:** | Electrosurgical Generator |
| **Classification Name:** | Electrosurgical Cutting and Coagulation Devices and Accessories (21CFR 878.4400; Class II; Product Code GEI) |
| **Predicate Devices:** | |
| Aaron Medical | Bovie IDS-300 Electrosurgical Generator (K-022856) |
| Bovie Medical | ICON GI (K-061884) |
| Valleylab | LigaSure Electrosurgical Generator (K-043273) |

## 510(k) SUMMARY (As Required per 21 CFR 807.92(c))

**DEVICE OPERATION:**

The Bovie ICON GP (the **Generator**) operates by delivering high frequency radiofrequency (RF) energy which, when used in conjunction with other electrosurgical accessories, is used to cut, coagulate, and seal tissues or vessels. There is a characteristic electrical wave form associated with each mode. The electrical properties of the waveform (frequency and duration) produce the clinical effect (i.e. cut, coagulation, seal). The shape and duration of waveforms are comparable between the generator and predicate devices.

The **Generator** functions in any of sixteen user selectable modes:

| | |
|---|---|
| 1. Pure Cut | 2. Blend Mode 1 |
| 3. Blend Mode 2 | 4. Blend Mode 3 |
| 5. Special Cut | 6. Laparoscopic Cut |
| 7. Pinpoint Coagulation | 8. Gentle Coagulation |
| 9. Spray Coagulation | 10. Laparoscopic Coagulation |
| 11. Macro Bipolar | 12. Micro Bipolar |
| 13. Gentle Bipolar | 14. Auto Stop Bipolar |
| 15. Vessel Seal | 16. Vessel Seal and Cut |

The generator is designed to comply with applicable Medical Electrical Equipment safety standards, including electromagnetic compatibility and other safety standards.

The Generator uses technology substantially equivalent to the predicate devices. The generator incorporates an ergonomically designed user interface screen for the selection of device settings. Although different from the user interface of the predicate devices, the difference does not affect the safety and effectiveness and may provide improved visualization of the device settings.

There are no new hazards presented with the use of the Bovie ICON GP generator as compared with the named predicate device.

**INTENDED USE:**

The Bovie ICON GP Generator is used to deliver high frequency radiofrequency energy in conjunction with other surgical devices for electrosurgical cutting, coagulation, or vessel sealing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 02 2008

Bovie Medical
% Mr. Richard A Kozloff
VP, Quality Assurance/Regulatory Affairs
7100 30th Avenue North
Saint Petersburg, Florida 33710

Re: K082109
Trade/Device Name: Bovie ICON General Purpose RF Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 22, 2008
Received: July 25, 2008

Dear Mr. Kozloff:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082109

Device Name: Bovie ICON General Purpose RF Generator

Indications for Use:

The Bovie ICON GP Generator is used to deliver high frequency radiofrequency energy in conjunction with other surgical devices for electrosurgical cutting, coagulation, or vessel sealing.

Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

~~(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)~~

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K082109